

REMARKS/ARGUMENTS

The present amendment is in response to the Office Action mailed August 22, 2002. A Renewed Petition to Revive under 37 CFR 1.137(b) with a four-month extension of time and a Request for Continued Examination are also submitted herewith.

Claims 1 and 3-22 were rejected in the outstanding Office Action. New claims 23-30 have been added and claims 1 and 3-22 have been cancelled herein. Support for added claims 23-30 may be found throughout the specification published as WO 98/05302, at for example, page 2, 2nd to 4th full paragraph, and page 3, last paragraph, to page 6. Therefore, no new matter has been added. Applicant respectfully requests entry of the amendment.

Claims 1 and 3-22 were rejected under 35 U.S.C. 102(b) as being anticipated by Schultz (WO 93/11747). Given that Applicant has cancelled claims 1 and 3-22 this rejection is moot. However, Applicant will discuss the merits of the cited prior art with regard to newly presented claims 23-30.

The Examiner argues that Schultz discloses a suspension aerosol formulation in which the drug is in particulate form, the fluorocarbon propellant is HFC 134a or HFC 227, and ethanol can be optionally included to about 20% with an optional surfactant. Further, the Examiner states that Example 8 discloses a canister containing pirbuterol acetate, HFC 227 and ethanol at 10% without a surfactant.

Applicant submits that newly added claims 23-30 are not anticipated by Schultz. Schultz does not disclose all elements arranged in the order prescribed by the newly presented claims. Newly added claim 23, the sole independent claim, requires:

an aerosol canister comprising a container closed with a metering valve, said container further comprising a pharmaceutical aerosol formulation substantially free of surfactant comprising, a bronchodilator selected from the group consisting of ephedrine,

adrenaline, fenoterol, formoterol,
isoprenaline, metaproterenol, phenylephrine,
phenylpropanolamine, pirbuterol,
reprocaterol, rimiterol, salbutamol,
salmeterol, terbutaline, isoetharine,
tolubuterol and orciprenaline or a salt
thereof, a fluorocarbon propellant, and 6%
to 25% of a polar co-solvent, and

**an actuator with a spray orifice aperture of
from about 100 to about 300 microns,**

(emphasis added).

Schultz does not disclose a pharmaceutical aerosol formulation substantially free of surfactant with an actuator having a spray orifice aperture of from about 100 to about 300 microns. In fact, *Schultz* does not disclose an actuator at all. Instead, *Schultz* refers to "Aerosol canisters equipped with conventional valves, preferably metered dose valves..." *Shultz* p.11, 1.13.

The most detailed disclosure in *Schultz* regarding the aerosol canister is set forth at page 11-12. In particular, p.11, 11.13-25 reads as follows:

Aerosol canisters equipped with conventional valves, preferably metered dose valves, can be used to deliver the formulations of the invention. It has been found, however, that selection of appropriate valve assemblies for use with aerosol formulations is dependent upon the particular surfactants or adjuvants used (if any), on the propellant, and on the particular drug being used. Conventional neoprene and buna valve rubbers used in metered dose valves for delivering conventional CFC formulations often have less than optimal valve delivery characteristics and ease of operation when used with formulations containing HFC 134a or HFC 227.

There is no disclosure of an actuator let alone spray orifice apertures therein having an aperture size within the claimed range. Therefore, there is no basis of lack of novelty based upon the *Schulz* publication. Applicant

therefore respectfully requests withdrawal of the rejection and allowance of claims 23-30.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone Applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: June 17, 2008

Respectfully submitted,

By 

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